Endoscopic visible light spectroscopy: optimizing the accuracy of diagnosing chronic gastrointestinal ischemia with luminal feeding stimulation (VLS-Study)

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- To determine the difference in baseline mucosal oxygen saturation measurements and after luminal feeding between patients diagnosed with CGI and healthy subjects. - To determine the difference in baseline mucosal oxygen saturation measurements...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Gastrointestinal vascular conditions
Study type	Observational invasive

Summary

ID

NL-OMON40460

Source
ToetsingOnline

Brief title
VLS-Study

Condition

- Gastrointestinal vascular conditions
- Arteriosclerosis, stenosis, vascular insufficiency and necrosis

Synonym
bowel ischemia, mesenteric ischemia

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: - chronic gastrointestinal ischemia, - diagnostic procedure, - mesentery blood flow, - mucosal oxygen saturation

Outcome measures

Primary outcome

- To determine the difference in baseline mucosal oxygen saturation

measurements and after luminal feeding between patients diagnosed with CGI and

healthy subjects.

- To determine the difference in baseline mucosal oxygen saturation

measurements prior to and after treatment inpatients diagnosed with CGI with

persistent relief of symptoms after treatment.

- To determine the microcirculatory perfusion before and 60 minutes after

luminal feeding in patients with and without CGI, using the following

measurement parameters:

Total vessel density (TVD [mm/mm2] or [cpll/mm2])

Perfused vessel density (PVD [mm/mm2] or [cpll/mm2])

Vessel diameters (VD [µm])

RBC velocity (RBCv [µm /sec])

Proportion of perfused vessels (PPV [%])

Microvascular flow index (MFI [AU])

Flow heterogeneity (MFIhet [AU])

Secondary outcome

Secondary endpoints:

- To determine normal mucosal oxygen saturation measurements of the antrum, duodenal bulb and descending duodenum in healthy subjects using visible light spectroscopy.

- To determine the effect of luminal feeding stimulation on mucosal oxygen saturation measurements of the antrum, duodenal bulb and descending duodenum in healthy subjects using visible light spectroscopy.

- Presence of abdominal pain before and after luminal feeding stimulation, using the Numeric Pain Intensity Scale to assess the pain severity.

- Time course response of luminal feeding stimulation on abdominal pain before and after 15 and 60 minutes of administering the compound liquid meal using the Numeric Pain Intensity Scale to assess the severity of pain. If pain is present, patients will be asked whether the pain is recognizable with the pain they experience after eating from before.

- Presence of abdominal pain before and after luminal feeding stimulation using the Numeric Pain Intensity Scale-score to assess the pain severity in patients treated for CGI.

- Time course response of luminal feeding stimulation on sublingual microcirculation before and 60 minutes of administering the compound liquid meal using the Cytocam hand-held microscope.

Study description

Background summary

Diagnosing chronic gastrointestinal ischemia remains a challenging quest.The standard diagnostic work-up of CGI suspected patients consists of clinical symptoms, radiological imaging and mucosal oxygen saturation measurement with visible light spectroscopy (VLS) in fasting state. With this diagnostic work-up detection of chronic gastrointestinal ischemia is acceptible, but better diagnostic methods with higher sensitivity are needed to identify patients. Several studies already have shown that patients with chronic gastrointestinal ischemia have an lesser increase in splanchnic blood flow after oral caloric stimulation compared to healthy subjects and that this leads to mucosal ischemia of the gastrointestinal tract . Mucosal oxygen saturation using endoscopic visible light spectroscopy after luminal feeding stimulation may thus lead to better identification of patients with chronic gastrointestinal ischemia .

Also, the microcirculation is the main site of oxygen delivery to tissue cells. Several studies have shown that microcirculatory alterations are related to hemodynamic changes which have been reported to impair intestinal perfusion (1-3). In these patients, the sublingual capillary perfusion seems well correlated to the hypoxic state of the gastric mucosa (4). However, these studies were performed in critically-ill patients with acute gastrointestinal ischemia. Up until now, no studies are performed to investigate the relationship between sublingual microcirculation and chronic hemodynamic changes such as in patients with CGI.
Therefore, sublingual measurement of the microcirculation can bring us more insight in the pathophysiology of gastrointestinal ischemia which may lead to development of new and less burdensome methods for the detection of gastrointestinal mucosal ischemia.

References:
1. Trzeciak S, McCoy JV, Phillip Dellinger R, et al. Early increases in microcirculatory perfusion during protocol-directed resuscitation are associated with reduced multi-organ failure at 24 h in patients with sepsis. Intensive Care Med. 2008 Dec;34(12):2210-7.
2. De Backer D, Donadello K, Sakr Y, et al. Microcirculatory alterations in patients with severe sepsis: impact of time of assessment and relationship with outcome. Crit Care Med. 2013 Mar;41(3):791-9.
3. Boerma EC, Kaiferova K, Konijn AJ, et al. Rectal microcirculatory alterations after elective on-pump cardiac surgery. Minerva Anestesiol. 2011 Jul;77(7):698-703.
4. Creteur J, De Backer D, Sakr Y, Koch M, Vincent JL. Sublingual capnometry tracks microcirculatory changes in septic patients. Intensive Care Med. 2006 Apr;32(4):516-23.

Study objective

- To determine the difference in baseline mucosal oxygen saturation measurements and after luminal feeding between patients diagnosed with CGI and

healthy subjects.
- To determine the difference in baseline mucosal oxygen saturation measurements prior to and after treatment inpatients diagnosed with CGI with persistent relief of symptoms after treatment.
- To asses sublingual microcirculatory alterations before and 60 minutes after luminal feeding stimulation in patients with and without CGI
- To determine whether there is a correlation between sublingual microcirculatory alterations and mucosal saturation measurements using VLS

Study design

A prospective cohort study to evaluate the diagnostic accuracy of visible light spectroscopy measurements after luminal feeding stimulation for detection of chronic gastrointestinal ischemia.
Patients suspected of chronic gastrointestinal ischemia referred to our hospital for further evaluation are asked whether they want to participate in our study in which next to the standard work-up, sublingual microcirculatory measurements using a videomicroscope and additional mucosal saturation measurements are performed after stimulation with luminal feeding.
The difference of mucosal oxygen saturation measurements and sublingual microcirculation measurements before and after luminal feeding stimulation will be compared for the overall group. The difference in mucosal oxygen saturation measurements for patients diagnosed with chronic gastrointestinal ischemia will be compared to the healthy volunteers. We then will investigate the value of the mucosal saturation measurement after luminal feeding in the diagnosis of chronic gastrointestinal ischemia.

Study burden and risks

Gastroduodenoscopy with baseline mucosal oxygen saturation measurements are already well accepted and incorporated in the standard work-up for patients suspected of CGI. A second gastroduodenoscopy with mucosal oxygen saturation measurement will therefore only take an additional 20 minutes and if patient is diagnosed and treated for CGI he will again be asked to for an additional gastroduodenoscopy with mucosal oxygen saturation measurements.
No additional visits to the hospital are required as the mucosal oxygen measurements with VLS for the standard work-up. The additional VLS and sublingual microcirculatory measurements will be performed during the same clinical setting, in doing so also limiting the total amount of conscious sedation and no longer duration of hospital stay is required.
Although most patients with CGI already present with postprandial pain in daily life, abdominal pain may occur when stimulation with luminal feeding begins. We will be well aware of this pain and ask patient several times if the pain occurs and stop if necessary.

Participation in this study will bring no additional benefit for the individual

patient.
However this study will provide valuable information on the predictive value and diagnostic accuracy of VLS measurements in the usual fasting condition and after feeding stimulation in the diagnosis of CGI. Therefore this test could be beneficial for the whole patient group since this prospective study may lead to identification and better recognition of patients with gastrointestinal ischemia and therefore could lead to more rapid treatment.
Performing mucosal saturation measurements in healthy subjects will make it possible to readjust and optimalize the current VLS cut-off values applied to diagnose patients with chronic gastrointestinal ischemia. This will be the first study to obtain baseline normal mucosal saturation values of different sites in the gastrointestinal tract actively excluding for confounders and reducing the risk of bias. Also we will be able to better understand the physiological differences between healthy subjects and patients with chronic gastrointestinal ischemia in their reaction to stimulation with food.

This prospective study will provide valuable information on the predictive value of VLS measurements and its power to select patients for treatment. It will also provide us more insight in the relationship between the microcirculation and hemodynamic changes in the gastrointestinal tract. This may lead to development of more rapid, less-burdensome and more advanced diagnostic methods for the detection of gastrointestinal ischemia.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- > 18 yrs of age
- capable of giving informed consent
- patients suspected of chronic gastrointestinal ischemia referred to the Erasmus MC for analysis of complains;Healthy volunteers:
- patent gastrointestinal arteries
- unremarkable medical history
- non-smoking

Exclusion criteria

- < 18 years
- Unable to give informed consent
- Patients with gastric (bypass) surgery
- Patients known with cardiac arrhythmias or cardiac conduction disease

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	05-08-2014
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	09-09-2013
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)
Approved WMO Date:	16-10-2014
Application type:	Amendment
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL43008.078.12